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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,214	03/20/2001	Kenneth Tucker	7969-089-999	1989

27144 7590 10/01/2004

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,214

Applicant(s)

TUCKER ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,13-16,27,29,35,40,52-54 and 57-63 is/are pending in the application.
- 4a) Of the above claim(s) 13-16,27,29,35 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,52-54 and 57-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 7/15/2004 has been entered.
2. Applicants' amendments and response of 7/15/04 are acknowledged. Specification pages 31, 53, 56-59, 61, -63, 65 and 85 have been amended. Claims 1, 4, 5 and 52 have been amended. Claims 11, 12, 19, 21, 34, 42-51 and 55-56 have been canceled. New claims 57-63 have been added.
3. Claims 1-8, 13-16, 27, 29, 35, 40, 52-54 and 57-63 are pending. Claims 13-16, 27, 29, 35 and 40 are withdrawn as being drawn to non-elected invention.
4. Claims 1-8, 52-54 and 57-63 are under consideration.

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Information Disclosure Statement

6. Applicants' Information Disclosure Statement of 7/15/04 is acknowledged. The references have been considered by the examiner, see attached PTO 1449.

Sequence Compliance

7. Applicants' CRF submitted 7/15/04 pursuant to sequence amendments is acknowledged. The CRF is technically flawed and have not entered into the database. On 9/20/04 the examiner

called attorney John M. Naber (reg # 46,487) in regard to the flawed CRF. On 9/21/04 attorney Robert Casad (reg# 51,535) responded and stated that a corrected CRF will be submitted.

Terminal Disclaimer

8. The terminal disclaimer filed on 7/15/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of full statutory term defined in 35 U.S.C. 154 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second application number 08/642,712 filed on May 3, 1996 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Rejections Moot

9. Rejections of claims 11-12, 19-21, 34, 42-51 and 55-56 under 35 U.S.C. 101 double patenting made in paragraphs 6 and 7 of the office action mailed 4/9/2003 are moot in view of cancellation of said claims.

10. Rejections of claims 11-12, 19-21, 34, 42-51 and 55-56 under judicially created doctrine of obviousness- type double patenting made in paragraph 8 of the office action mailed 4/9/2003 is moot in view of cancellation of said claims.

11. Rejections of claims 19, 42-43, 46-49 and 55-56 under 35 U.S.C. 112 first paragraph made in paragraph 10 of the office action mailed 4/9/2003 is moot in view of cancellation of said claims.

Rejections Withdrawn

12. Rejection of claims 1-8 and 52-54 under 35 U.S.C. 101 double patenting made in paragraphs 7 of the office action mailed 4/9/2003 is withdrawn in view of cancellation of conflicting claims in copending application number 08/642,712.

13. Rejections of claims 1-8 and 52-54 under judicially created doctrine of obviousness- type double patenting made in paragraph 8 of the office action mailed 4/9/2003 withdrawn in view of applicants' terminal disclaimer.

14. Rejection of claims 1-8 and 52-54 under 35 U.S.C. 112 first paragraph made in paragraph 11 of the office action mailed 4/9/2003 is withdrawn in view of applicants amendments.

***New Objections
Specification***

Note: There are two set of specification in the electronic version of this application. There is a 71 page specification which has been arrived on March 20, 2001 and the recent amendments sent on 7/15/2004 by the applicants corresponds to the pages that applicants haven been trying to amend. But there is also a 54 page specification that has been arrived on October 8, 2003, which does not correspond, to the amendments sent on 7/15/2004. Therefore, the recent amendments to the specification can be considered non responsive. Clarification is requested on this important matter.

15. The disclosure is objected to because of the following informalities:

The specification is objected to for presenting a Table of Contents that refer to the specification by page number. This table of content is not appropriate because patents are not provided by page number and thus renders the references to pages confusion. Applicants are required to delete these pages or provide substitute pages that delete the references to specific page numbers of the specification.

The use of trademark ATCCTM has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate corrections are required.

New Rejections

Rejection(s) under 35 U.S.C. 112, first paragraph

16. Claims 1-8 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are now drawn to any isolated polypeptide of *Moraxella catarrhalis*, wherein said polypeptide is an outer membrane polypeptide of *Moraxella catarrhalis*, and has a molecular weight of about 180 kD to about 230 kD. The claims encompass polypeptides whose molecular weight is determined by any means. The art provides for multiple means of determination of "apparent" molecular weight. These means are sodium-dodecyl sulfate polyacryamide gel electrophoresis with specific markers, actual molecular mass by means of calculation based on the weights of the sum total of the individual amino acids present, the apparent molecular weight as determined by gel filtration chromatography. The identical protein as ascertained by these different methods will have different apparent molecular weights. Applicants' specification has not provided for molecular weight assessment

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by these other means. Applicants own specification indicates that the methods used to assess molecular weight provide for different determination of apparent molecular weight (see page 16). As such, there is no conception of proteins having the claimed molecular weight wherein the assessment is made by means other than sodium dodecyl sulphate polyacrylamide gel electrophoresis using rabbit skeletal muscle myosin and E. coli beta-galactosidase as the 200 kD and 116.25 kD molecular weight standards, respectively. The specification does not conceive any other means of identification or isolation of apparent molecular weight by any other means. As such, because these other means would lead to different apparent molecular weight determinations and moreover would include polypeptides not disclosed herein, the specification does not support the now recited genus claim.

17. Claims 57-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to isolated polypeptides or fragments thereof that are produced recombinantly. In order to produce the polypeptide or fragments thereof recombinantly, the corresponding nucleic acid is required. The specification fails to disclose any nucleic acid sequence that encodes an isolated polypeptide of *Moraxella catarrhalis* wherein said polypeptide is an outer membrane protein and has a molecular weight of about 180 kD to about 230 kD. The teachings of the specification are limited to amino acid sequence consisting of SEQ ID NOs: 1 and 2, which correspond to the specific polypeptide fragments of the claimed outer membrane polypeptide from the American

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Type Culture Collection No. 49143. The nucleic acids sequence encoding these specifically limited peptide fragments have written description. However, generic fragments and the entirety of the polypeptide fail to meet the written description and enablement provisions of 35 U.S.C. 112, first paragraph because neither the entire polypeptide nor all the fragments thereof have been described by chemical means and as such claims reciting recombinant production of the polypeptide likewise fail to meet the written description provision of 35 U.S.C. 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed" (see page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116.)

With the exception of the peptide fragments consisting of SEQ ID NO: 1 or 2, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins and polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. see Fiers v. Revel. 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. see Fiddes v. Baird, 30 USPQ2d

1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. This specification fails to provide a description of a complete nucleic acid or complete protein sequence for any species that falls within the claimed genus. As such, the specification lacks written description for recombinant polypeptide or generic recombinant polypeptide fragments.

18. Claims 1-8, 52-54 and 60-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term about in claims 1, 2 is a relative term, which renders the claims indefinite.

Claim 1 is prima facie indefinite because the claim fails to recite how the apparent molecular weight was determined. The skilled artisan is well aware that "apparent" molecular weight is highly impacted by the method and means by which it is determined. For example, the same protein would have different molecular weights when assessed by reducing sodium dodecyl sulfate polyacrylamide gel electrophoresis and gel-exclusion chromatography because the gel exclusion chromatography provides for folding of the protein into secondary and tertiary structure that would directly impact the resultant apparent molecular weight. As such, in the absence of how the molecular weight was ascertained, one skilled in the art would not be able to ascertain with any certainty the subject material included or excluded by the claim.

Claims 3 and 4 are rejected under 35 U.S.C. 112 second paragraph as being indefinite from the use trade mark ATCCTM. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Claims 5-8, 52-54 and 60-63 are indefinite as being dependent from rejected claim 1.

Rejection under 35 U.S.C 103 (a)

19. Claims 1-8, 52-54 and 60-63 are rejected under 35 U.S.C. 103 (a) as being obvious over Sasaki et al. (U.S. Patent No. 6,335,018, 6, 440, 424 and 6, 440, 425).

The claims are drawn to an isolated and purified outer membrane from *Moraxella catarrhalis*.

Sasaki et al. '081 teaches an isolated and purified outer membrane from *Moraxella catarrhalis* having a molecular mass about 200 kDa as determined by sodium dodecyl sulfate polyacrylamide gel electrophoresis (see claim 1). Sasaki et al. teach purification of the polypeptide to at least 70 weight percent or at least 95 weight per cent (see claims 4 and 5). The "about" language encompasses the 99% purity limitation as specially recite in claims 1 and 57. Sasaki et al teach a peptide fragment of the polypeptide (see claim 9). Sasaki et al teach the production of the polypeptide and the fragments by recombinant or synthetic means (see claim 8 and example 8) using disclosed nucleic acid. With respect to claims 7, 8, 52 and 58, these claims are obvious over in view of the common epitopes of the polypeptide of Sasaki et al. and SEQ ID NO: 1. Antibodies binding these common epitopes would necessarily bind the homologous polypeptide. Sasaki et al. do not explicitly teach limitations such extraction of polypeptides from intact cells at room temperature in 1.25% w/v n-octyl glucoside. Limitations such as mentioned above are being viewed as limitations of optimizing experimental parameters.

It would have *prima facie* obvious to a person of ordinary skill in art at the time the invention was made to isolate the claimed polypeptides from other known strains of *Moraxella* to obtain the claimed invention. One of ordinary skill in art would have been motivated with the reasonable expectation of success to extract the claimed polypeptide by the method known in the art by optimizing experimental parameters any convincing evidence to the contrary.

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Note: Each of Sasaki et al. '424 and '425 teach the same material as recited and relied upon in the '018 Sasaki et al. patent. As such, each of the claims are alternatively rejected under all of these three patents.

Conclusion

20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

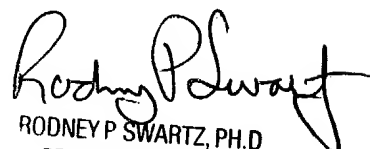
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

September 23, 2004


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER